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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,777	10/23/2000	Luis Angel Pardo-Fernandez	MPG-8	8515

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EXAMINER
WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
1647	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/694,777	Applicant(s) PARDO-FERNANDEZ ET AL.	
	Examiner Sandra Wegert	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *11-13,16-31 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,14,15 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Information Disclosure Statement submitted 10/23/00 (Paper 5) has been entered into the record. Applicant's election with traverse of Invention I, (claims 1-10, 14, 15 and 32) in Paper No. 12 (11/30/01) is acknowledged. In addition, Applicant elected the following Group: SEQ ID NO: 14. The Applicant traversed the restriction in which claim 8 was placed with both Invention I and Invention II since the claim encompasses both single-celled recombinant organisms and transgenic mammals, for example. However where Claim 8 (Invention II) reads on a transgenic multicellular animal, it is properly restricted from the nucleic acid/host cell invention of Group I because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. Generally, the host cell is used to produce a polypeptide for harvesting or for cellular assays of function, while a transgenic mouse, for example, might be used in tests of the physiological role of an expressed peptide.

Claims 1-10, 14, 15 and 32 are under examination in the current application.

Informalities

Specification

The disclosure is objected to because of the following informalities:

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "HUMAN K+ ION CHANNEL OF THE EAG FAMILY".

Appropriate correction is required.

Sequence Rules

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, especially 1.821, part (c), because each disclosure of a sequence embraced by the definitions set forth in the rules must be accompanied by the required reference to a unique sequence identifier (i.e., SEQ ID NO:). This occurs in Claim 2, throughout the specification (page 9, line 31; page 11, line 19; page 33, line 21, for example) and in Figures 10 and 11. SEQ ID NO's corresponding to figures may be placed within the figures themselves or in the Brief Description of Figures.

Appropriate correction is required.

Claim Rejections/Objections

Claim Objections-

Claims 1, 8, 14, 15 and 32 are objected to because they recite or encompass non-elected inventions.

Appropriate correction is required.

35 *USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1-10, 14, 15 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for making or using all of the possible polypeptides or polynucleotides as indicated in claims 1-10, 14, 15 and. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence

or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The breadth of claims 1-10, 14, 15 and 32 is too large. Since claim 1(c) recites no stringency conditions for the recited polynucleotide, the claims read on polynucleotides that bind under low-stringency conditions, or even under no-stringency conditions. However, the specification fails to provide any guidance on how to produce all nucleotides that hybridize under low-stringency conditions, and still retain the functions of the claimed polynucleotides. In addition, the scope of Claims 1-10, 14, 15 and 32 is large because the claims do not recite functional activity, which would serve to further define the invention and limit its scope.

Likewise, the breadth of claims 3-10, 14, 15 and 32 is too large in that they read on the primer sequence of claim 2. The specification does not disclose how to make the all polynucleotides that would comprise the short nucleic acid recited in claim 2.

In summary, the specification does not provide a description of a repeatable process of producing, nor of working examples of making, all possible nucleic acids encompassed by claim 1(c) in which stringency conditions are not specified. In addition, no functional language was recited, such that the scope of the claims can be determined. For these reasons, undue experimentation would be required to make all possible proteins encompassed by the claims and to determine a structure-function relationship for each possible polypeptide or polynucleotide.

Furthermore claim 15 is not enabled by the specification because the subject matter was not described in such a way as to enable one skilled in the art to which it pertains, or with which

it is most nearly connected, to make and/or use the invention. The specification is not enabling for the limitation of the claims wherein a composition comprising a nucleic acid, polypeptide or antibody is used in diagnosis.

Claims 15 reads on a composition for diagnosis comprising the nucleic acids, polypeptides, or antibodies recited in previous claims.

The specification discloses the nucleic acid and amino acid sequences of a K^+ channel of the *eag* family. The specification also describes experiments in which cells, transfected with the *eag* K^+ channel, demonstrated *eag* channel activity under patch-clamp conditions, and responded to art-recognized ligands for this channel type.

However, the claim recites use of a composition of nucleic acids, polypeptides, and/or antibodies for "diagnosis". There is no enabling discussion or working examples disclosed in the instant application as to how or what disease is related to the *eag* K^+ channel disclosed in the specification, nor is there discussion of how one would practice the method of diagnosing a disease.

Due to the large quantity of experimentation required to determine how to use the disclosed sequences to diagnose a condition, the lack of direction or guidance in the specification regarding the same, the lack of working examples that identify or diagnose a condition, the state of the art which is silent concerning diseases related to this channel, and the breadth of the claim which embraces potentially many diseases --undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-9 and 10 are rejected under 35 U.S.C. 102(b) as being unpatentable over Warmke, et al (1994, PNAS., 91:3438-3442; see Fig 1). Warmke et al disclose a potassium channel bearing 45.0-51.2 percent sequence homology with the disclosed potassium channel (SEQ ID NO: 14) of the Instant Invention. This reference meets the limitations of claim 1 and dependent claims in which hybridization stringency conditions are not recited, as well as reading on the recited host cells and recombinant methods of claims 9 and 10.

Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rendered indefinite because, while it is useful to make a complement to a degenerate sequence, it is difficult to contemplate the nature of a degenerate sequence of a complement.

Claim 2 is rendered indefinite because there is no antecedent basis for "The" nucleic acid. There are several nucleic acids that comprise the recited sequence and still hybridize specifically. However, it is not clear which one nucleic acid is claimed.

Claim 8 is rendered indefinite because it is not clear the type of organism indicated by the word "host".

Claim 10 is rendered indefinite because the specification does not teach how to recombinantly produce a polypeptide from the complementary nucleic acid (refer to Claim 1(c) and Claim 2).

Claim 14 is rendered indefinite because there is no antecedent basis for "The" antibody, since many antibodies can be made against the recited polypeptide.

Claims 14, 15 and 32 are indefinite under 37 CFR 1.75, for being of improper dependent form by use of "and/or"; a claim must refer to previous plural claims in the alternative only. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Conclusion:

Claims 1-10, 14, 15 and 32 are rejected for the reasons listed above.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

12/7/01

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER